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*Admitted only in Maryland
+Admitted only in Virginia
•Practice Limited to Federal Agencies

October 7, 2005

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Supplement to Citizen Petition Concerning Pending New Drug Application For PATANASE® (Olopatadine Hydrochloride Nasal Spray)
Docket No. 2005P-0409

Dear Sir/Madam:

We are hereby submitting the enclosed supplement to our Citizen Petition filed October 5, 2005, concerning the proposed trade name PATANASE®, which is currently part of a pending new drug application for olopatadine hydrochloride nasal spray. In accordance with 21 C.F.R. §10.30, this original Citizen Petition is accompanied by five (5) copies thereof; it is respectfully requested that one copy be stamped with the date of receipt thereof by the U.S.F.D.A., and returned to the undersigned in the accompanying self-addressed stamped envelope.

Sincerely,

Jorge Goldstein, Ph.D., Esq.
Brian J. Del Buono, Ph.D., Esq.

cc: Badrul Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
HFD-570

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2005P-0409

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Re: Supplement to Citizen Petition Concerning
Pending New Drug Application for PATANASE®
(Olopatadine Hydrochloride Nasal Spray)
Docket No. 2005P-0409

Dear Sir/Madam:

As permitted by 21 C.F.R. § 10.30(g), we are hereby supplementing the citizen petition that we submitted on October 5, 2005 ("Citizen Petition"). The Citizen Petition requested the Commissioner of Food and Drugs to refrain from accepting the proposed trade name PATANASE® as part of a pending new drug application ("NDA") for olopatadine hydrochloride nasal spray submitted by Alcon, Inc. ("Alcon"). The following supplementary information provides additional grounds for the request.

In the Statement of Grounds, our Citizen Petition identified a number of existing product trade names with which PATANASE® could be confused. In addition to the trade names noted in the original petition, the proposed name PATANASE® also could readily be confused with PATANOL®, olopatadine hydrochloride ophthalmic solution 0.1%, which has been marketed for a number of years by Alcon. The two drug names obviously both begin with the same "Patan" element. Written prescriptions would be subject to a significant potential for confusion, particularly in light of the common practice of "trail off" in writing drug names on prescriptions. Verbal prescriptions also could be misheard by pharmacists, who may automatically think "Patanol" even though the speaker intends to be saying "Patanase." In addition, given the similarity of the names, and the long marketing history of PATANOL®, the prescriber may actually verbalize or write "Patanol" even though he or she intends to be prescribing the new product, PATANASE®. Written or verbal prescriptions for PATANOL® could be similarly

confused. The potential for confusion between the two trade names is significantly enhanced by the identity of the active ingredient, the similarity in indications (seasonal allergic rhinitis for PATANASE® and allergic conjunctivitis for PATANOL®) and the fact that the same patient could be a candidate for either or both drugs.

A patient for whom PATANASE® is prescribed, but who erroneously is dispensed PATANOL® by the pharmacist would fail to receive adequate treatment. A typical prescription may be written (or verbally conveyed) as follows:

Patanase
Sig: Administer as directed

However, the pharmacist may erroneously dispense PATANOL®, which is a 0.1% solution meant to be administered into the eye. The patient then may drop the product into the nose as his doctor directed him to do (we assume that the doctor told the patient he was prescribing a nasal product). Under these circumstances, the likely outcome is that the patient will have a lack of therapeutic effect from the treatment. The reason is that PATANASE®, which was the intended product, has a much higher (6 fold) concentration than the 0.1% PATANOL® that was actually dispensed. FDA considers "lack of therapeutic effect" to be an adverse experience by definition. In addition, the lack of intended effect in general raises health care costs, which is inconsistent with good public health policy.

Alternatively, a patient for whom PATANOL® is prescribed, but who is erroneously dispensed PATANASE® by the pharmacist, would also experience adverse effects. A typical prescription may be written (or verbally conveyed) as follows:

Patanol
Sig: Administer as directed

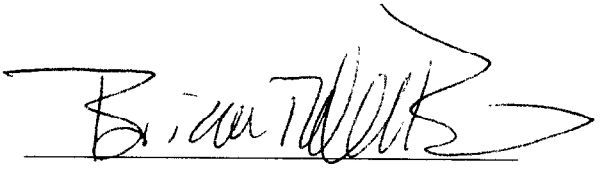
However, the pharmacist may erroneously dispense PATANASE®, which is a 0.6% preparation meant to be administered into the nose. The patient may still attempt to spray the product into the eye, because the doctor told him he was prescribing an eye preparation. In this situation there would be adverse reactions due to misuse of a product meant for intranasal use only. Possibly severe stinging, burning, and eye pain would result because the nasal product: (1) is not formulated as an ophthalmic and hence is very hypertonic and (2) the concentration of 0.6% is 6 times stronger than the 0.1% concentration that the doctor intended when he expected the patient to receive the eye drops.

In both of the above examples, the confusion caused by similarly named products for similar therapeutic conditions can result in either lack of benefit to the patient or eye injury (or at

very least, great discomfort). Both are examples of significant medication errors caused by potential trade name confusion.

Thank you for including this supplement to our Citizen Petition in Docket No. 2005P-0409.

Respectfully submitted,



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